

### **REMARKS**

Claims 1, 3-11 are pending. Claim 2 has been withdrawn as assertedly directed to non-elected subject matter, and such withdrawal is traversed herein. Claims 1, 2, 6 and 11 have been amended. No new matter has been added. Claims 12-17 have been canceled without prejudice. Applicants respectfully reserve the right to file continuing applications.

Applicant respectfully submits that entry of the above claim amendments is proper under 37 C.F.R. § 1.116 because the amendments: (a) place the application in condition for allowance (for the reasons discussed herein); (b) do not raise any new issues requiring further search and/or consideration (since the amendments amplify issues previously discussed throughout the prosecution), except to the extent that searches for up to additional 10 variant sequences within this application is reasonable pursuant to 37 C.F.R. §1.141 and MPEP 803.04; (c) do not present any additional claims without canceling a corresponding number of finally rejected claims; and (d) place the application in better form for appeal. Thus, entry of the foregoing amendments, reconsideration and reexamination of the claimed subject matter are respectfully requested.

### **Interview**

Applicants gratefully acknowledge the Examiner's time and consideration in granting an interview on September 28, 2004 and October 13, 2004. The September 28th interview is briefly summarized in conjunction with the traversal of the rejection under 35 U.S.C. §102 below. In the October 13th interview the rejections under 102, 101 and 112 were discussed, along with the restriction/election requirement with regard to variants. It was agreed that with respect to the 102 rejection that the claimed invention is not anticipated by Millar et al. and that the terms "having the" refer to the entire SEQ ID NO:9.

### **Objections**

Claims 2 is objected to for assertedly including subject matter which has been non-elected due to a restriction requirement and therefore, the non-elected subject matter has been assertedly withdrawn from consideration. Applicants traverse this withdrawal to the extent the herein presented claim 2 is directed to elected subject matter. In particular, claim 2 as presented herein is directed to a variant comprising at least one copy of a polynucleotide having the sequence of, *inter alia*, SEQ ID NO:10. SEQ ID NO:10 is the complement to SEQ ID NO:9, and as such, these two sequences encode the same protein. Pursuant to MPEP §803.04 those

sequences that are patentably indistinct from the selected sequence will be examined in a single application.

Other variants disclosed in claim 2 share the common novel aspect of the elected invention, the isolated insulator sequence of SEQ ID NO:9 (NI16). SEQ ID NO:1 contains two repeats of the palindromic insulator sequence of SEQ ID NO:9. Likewise, SEQ ID NO:5 contains one copy of the palindromic insulator sequence of SEQ ID NO:9. SEQ ID NO:11 is a 29 base pair native insulator (NI29) which also contains the 16 base pair native palindromic insulator sequence of SEQ ID NO:9. SEQ ID NO: 12 is merely the complement to SEQ ID NO:11 and is therefore not patentably distinct from SEQ ID NO:11. Accordingly, Applicants respectfully request withdrawal of the objection to claim 2 for not being directed to elected subject matter.

Applicants reiterate that in view of the species election to SEQ ID NO:9 and upon a finding that claims directed to SEQ ID NO:9 are allowable, the Examiner should examine a reasonable number of nucleotide sequences pursuant to the partial waiver of the requirements of 37 C.F.R. §1.141 *et seq.*, which reasonable number of sequences to be examined in a single application without restriction has been determined to be up to ten sequences. Applicants respectfully submit that there are less than 10 patentably distinct variants set forth in claim 2 which would require further searching. As set forth above, SEQ ID NOS: 1, 5 and 11 share a common novel aspect of the claimed invention (i.e., SEQ ID NO:9) and would therefore be identified by the search of SEQ ID NO:9. SEQ ID NOS: 15 (M1), 17 (M2), 21 (M4), 23 (M5), 25 (M6) and 27 (M7) are mutants of SEQ ID NO:9 containing mutations of one to three nucleotides. SEQ ID NOS: 12, 16 (M1), 18 (M2), 22 (M4), 24 (M5), 26 (M6) and 28 (M7) are the respective complements to SEQ ID NOS: 11, 15, 17, 21, 23, 25 and 27, and therefore are patentably indistinct since they encode the same protein respectively. That is SEQ ID NOS 11 and 12 encode the same protein, SEQ ID NOS: 15 and 16 encode the same protein, SEQ ID NOS: 17 and 18 encode the same protein, SEQ ID NOS: 21 and 22 encode the same protein, SEQ ID NOS: 23 and 24 encode the same protein, SEQ ID NOS: 25 and 26 encode the same protein, and SEQ ID NOS: 27 and 28 encode the same protein.

Furthermore, SEQ ID NOS: 30, 31, 33, 34, 35 and 36 encode the same core structure, the insulator mutant sequence of SEQ ID NOS: 15 (M1), 17 (M2), 21 (M4), 23 (M5), 25 (M6) and 27 (M7), and therefore would not require further searching beyond searching of SEQ ID NOS:

15, 17, 21 23, 25 and 27. Accordingly, Applicants respectfully request examination of all the variants of claim 2 in this application upon allowance of the elected species.

**Rejections Under 35 U.S.C. §101**

Claims 6 and 7 are rejected under 35 U.S.C. §101 as allegedly being directed to non-statutory subject matter. Applicants traverse this rejection for at least the following reasons. Courts have long held that isolated and purified products of nature are patentable compositions of matter. See, e.g., Diamond v. Chakrabarty 447 U.S. 303 (1980). Claim 6 as originally provided is directed to a host cell comprising an isolated polynucleotide product. As such, the host cell cannot occur in nature as it contains within it an isolated sequence which itself does not occur in nature, but which has been manipulated by the hand of man and transformed into the host cell. Notwithstanding, claim 6 has been amended to recite, “A host cell comprising the replicable vector of claim 3”. Accordingly, Applicants respectfully submit that the claimed invention is not directed to non-statutory subject matter and requests reconsideration and withdrawal of the rejection.

**Rejections Under 35 U.S.C. §112, second paragraph**

Claims 1-11 are rejected under 35 U.S.C. §112, second paragraph (indefiniteness), as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular, the Office Actions assertedly finds the phrase “its complement” unclear in regard to what it refers to. Applicants respectfully traverse this rejection to the extent it applies to the herein claimed invention. Claims 1 and 11 have been amended to state, “wherein said variant hybridizes to SEQ ID NO:9 or the complement of SEQ ID NO:9”. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection.

**Rejections Under 35 U.S.C. §112, first paragraph**

Claims 1- 11 are rejected under 35 U.S.C. §112, first paragraph (written description), as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicants respectfully traverse this rejection for at least the following reasons.

The Patent Office guidelines for written description of a claim drawn to a genus, like a genus of variants, set out that written description of a genus may be satisfied through description of a representative number of species by actual reduction to practice, **or** by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. See MPEP §2163 II.A.3.(a) ii). Moreover, Vas-Cath v. Mahurkar, 935 F.2d 1555 makes clear that the applicant need not describe exactly the subject matter claimed, but the description must clearly allow persons of ordinary skill in the art to recognize that applicants invented that which is claimed. In that regard, “a specification may, within the meaning of 35 U.S.C. §112 para. 1, contain a written description of a broadly claimed invention without describing all species that the claim encompasses.” See Vas-Cath, 935 F.2d at 1563, citing Kennecott Corp. v. Kyocera Int’l, Inc., 835 F.2d 1419.

It is respectfully submitted that Applicants have provided a description of a representative number of species variants **and** have disclosed identifying characteristics of variants by structure and function to enable persons of ordinary skill in the art to recognize the claimed invention. First, contrary to the Office Action’s assertion that Applicants, with the exception of SEQ ID NO:9, have not adequately described variants other than by a mere statement that they are part of the of the invention and reference to a potential method of isolation, Applicants provide examples of representative species of variants actually reduced to practice by Applicants in at least Table 1 and Table 3 of the specification in a mature field. It is respectfully submitted that Applicants have set forth the sequence structure for a representative number of variants with sufficient variety that one of ordinary skill and knowledge in the art would recognized that Applicants were in possession of the claimed invention at the time of filing.

Second, identifying characteristics of variants are found on at least page 5, paragraph [19] which sets out that variants hybridize to SEQ ID NO:9 under certain hybridization conditions and have insulator activity. A person of skill in the art would not expect substantial variation among species encompassed within the scope of the claims because the hybridization conditions (i.e., 5x SSC and 42°C wash conditions) in combination with the coding function of DNA (i.e., insulator activity) and the level of skill and knowledge in the art at the time of filing are adequate to determine that Applicants were in possession of the claimed invention at the time of filing.

Moreover, the disclosed sequence specific representative species together with the identifying characteristics of the variants is sufficient to show that the Applicants were in possession of the claimed invention at the time of filing. Accordingly, Applicants respectfully submit that there is written description of the claimed invention and Applicants respectfully request reconsideration and withdrawal of the rejection.

**Rejections Under 35 U.S.C. §102**

Claims 1-11 are rejected under 35 U.S.C. §102 as allegedly being anticipated by Millar et al. (May 1999). Applicants traverse this rejection for at least the following reasons. In an interview of September 28, 2004 the Examiner explained that the rejection in view of Millar et al. was to the first element of the claim 1, which is directed to a polynucleotide having the sequence set forth in SEQ ID NO:9. It is respectfully submitted that the terms “having the” refer to the complete sequence of SEQ ID NO:9. Millar et al. merely discloses a part or fragment of SEQ ID NO:9, and therefore the claimed invention is not anticipated by Millar et al.. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection.


**CONCLUSION**

Early consideration, entry of the Amendment and Reply After Final, favorable consideration and prompt allowance of the pending claims are respectfully believed to be in order and respectfully requested. If anything else is necessary to place this application in condition for allowance, e.g., by Examiner's Amendment, Applicant respectfully requests that the Examiner contact the undersigned representative at the telephone number listed below.

**To the extent necessary, please grant any extension of time deemed necessary for entry of this communication. Please charge any deficient fees, or credit any overpayment of fees, to Deposit Account 500417.**

Respectfully submitted,  
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